# **CLOBETASOL CREAM**

Clobetasol Propionate (0.05% w/w)

#### What is in this leaflet

- 1. What Clobetasol Cream is used for
- 2. How Clobetasol Cream works
- 3. Before you use Clobetasol Cream
- 4. How to use Clobetasol Cream
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of Clobetasol Cream
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

#### What Clobetasol Cream is used for

Treatment of more resistant skin conditions, such as psoriasis (autoimmune condition that causes the rapid buildup of skin cells), eczemas, lichen planus, discoid lupus erythematosus and other conditions which do not respond satisfactorily to less active steroids.

#### **How Clobetasol Cream works**

Corticosteroids give anti-inflammatory effects to topical application.

#### Before you use Clobetasol Cream

- When you must not use it

Do not use Clobetasol Cream if:

- You have facial redness
- You have acne and bumps around the mouth.
- Skin inflammation in children under 1 year, including napkin eruptions.
- Skin lesions caused by infection with viruses (such as herpes simplex, chickenpox), fungi (such as candidiasis, tinea) or bacteria (such as impetigo (skin infection that mainly affects infants and children)).
- Hypersensitivity to Clobetasol or other ingredients in the preparation.

## Pregnancy and lactation

Do not take Clobetasol Cream if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Clobetasol Cream if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it
- Long term continuous therapy with corticosteroid preparations should be avoided, particularly in infants and children, in whom adrenal suppression occurs readily.

- If corticosteroid preparations are required for use in children, it is recommended that the treatment should be reviewed weekly.
- If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as increased in eye pressure might result.

## - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

#### How to use Clobetasol Cream

#### - How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

#### - When to use it

Use once or twice daily until improvement occurs or as directed by your doctor or pharmacist.

## - How long to use it

As with other highly active topical steroid preparations, therapy should be discontinued when control is achieved. In the more responsive conditions, this may be within a few days. If a longer course is necessary, it is recommended that treatment should not be continued for more than 4 weeks without the condition being reviewed.

Continue taking Clobetasol Cream for as long as your doctor recommends.

### - If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Apply it as soon as you remember. If it is almost time for your next dose, wait until then to apply the cream and skip the missed dose. Do not take a double dose to make up for the missed dose.

# - <u>If you use too much (overdose)</u>

For topical application of corticosteroids, problems of overdosage are unlikely to be encountered. Gradual withdrawal of the preparation may be necessary. Consult the doctor immediately if any unusual serious reactions happened.

#### While you are using it

#### - Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking Clobetasol Cream.

Tell your doctor immediately if you become pregnant while taking this medication.

#### - Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Clobetasol Cream to anyone else, even if they have the same symptoms or condition as you.

# - Things to be careful of

Any spread of infection requires withdrawal of Clobetasol Cream and you need to consult the doctor.

Gradual withdrawal of the preparation may be necessary.

#### **Side effects**

Like all medicines, Clobetasol Cream can cause side effects, although not everybody gets them.

Prolonged and intensive treatment with highly active corticosteroid preparations may cause skin changes, such as stretch mark, thinning of the skin and dilatation of the superficial blood vessels, particularly when occlusive dressings are used, or where skin folds are involved. In rare instances, treatment of psoriasis with corticosteroids is thought to have provoked the pus. Use of occlusive dressing increases the absorption of topical corticosteroids. In infants, the napkin may act as occlusive dressing.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website <a href="mailto:npra.moh.gov.my">npra.moh.gov.my</a> (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI).

# **CLOBETASOL CREAM**

Clobetasol Propionate (0.05% w/w)

# Storage and Disposal of Clobetasol Cream

## - Storage

Keep out of reach of children. Keep container tightly closed. Store in a dry place below 30°C. Protect from light. For external use only

# - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **Product Description**

# - What it looks like

White in colour cream with natural odour.

- Ingredients
- Active ingredient Clobetasol Propionate
- Inactive ingredients White Soft Paraffin, Liquid Paraffin, Deionised Water, Chlorocresol, Glycerin, Cetomacrogol Emulsifying Wax

# - MAL number:

MAL19961875AZ

# Manufacturer & Product Registration Holder

Dynapharm (M) Sdn. Bhd. 2497, Mk 1, Lorong Perusahaan Baru 5, Kawasan Perusahaan Perai 3, 13600 Perai, Pulau Pinang, Malaysia.

## **Date of revision**

27/07/2018

# Serial Number:

NPRA(R4/1)190718/00201